## Plaintiffs' Memorandum in Opposition to Joint Motion for Summary Judgment for Failure to Prove Fault Element of Public Nuisance Claims

Ex 40 - MCKMDL00337001-024

# SETTLEMENT AND RELEASE AGREEMENT AND ADMINISTRATIVE MEMORANDUM OF AGREEMENT

This Settlement and Release Agreement and Administrative Memorandum of Agreement ("Agreement") is entered into on this 2 day of May 2008, by and between the United States Department of Justice, Drug Enforcement Administration (hereinafter "DEA") and McKesson Corporation including facilities doing business as McKesson Pharmaceutical and McKesson Drug Company (hereinafter "McKesson") (each a "Party" and collectively the "Parties").

#### APPLICABILITY

This Agreement shall be applicable to McKesson and all McKesson DEA registered facilities as identified in Appendix A.

#### BACKGROUND

WHEREAS, on August 4, 2006, DEA, by its Deputy Assistant Administrator, Joseph T. Rannazzisi, issued an Order to Show Cause ("Order #1") to McKesson, with respect to its Lakeland distribution center located at 1515 West Bella Vista Street, Lakeland, Florida 33805 (the "Lakeland Facility"); and

WHEREAS, Order #1 alleged, among other things, that McKesson failed to maintain effective controls at the Lakeland Facility against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain customers of McKesson; and

WHEREAS, after service of Order #1 on McKesson, representatives of DEA and McKesson entered into discussions on how best to resolve the issues raised in the Order; and

WHEREAS, on November 1, 2007, DEA, by its Deputy Assistant Administrator, Joseph T. Rannazzisi, issued a second Order to Show Cause to McKesson ("Order #2," and "Orders" when jointly referring to Order #1 and Order #2), with respect to its Landover distribution center located at 7721 Polk Street, Landover, Maryland, 20785 (the "Landover Facility"); and

WHEREAS, Order #2 alleged, among other things, that McKesson failed to maintain effective controls at the Landover Facility against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain customers of McKesson; and

WHEREAS, DEA alleges that McKesson failed to maintain effective controls at its Conroe, Texas distribution center (the "Conroe Facility") against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain customers of McKesson; and

WHEREAS, DEA alleges that McKesson failed to maintain effective controls at its Denver, Colorado distribution center (the "Denver Facility") against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain customers of McKesson; and

WHEREAS, DEA alleges that McKesson has failed to report suspicious orders of controlled substances and to report thefts or significant losses of controlled substances as more fully set forth in Appendix B, Paragraph 8 as required by 21 C.F.R. 1301.74(b); and

WHEREAS, McKesson is registered with DEA at 39 facilities as distributors of Schedule II-V controlled substances under the provisions of the Comprehensive Drug Abuse Prevention Control Act of 1970, Title 21 U.S.C. § 801 et seq., ("CSA" or "the Act"); and

WHEREAS, McKesson denies the allegations set forth in the Orders and as otherwise summarized above and also denies any allegations of improper conduct including but not limited to allegations that it failed to maintain effective controls against diversion or failed to file suspicious order reports; and

WHEREAS, the Parties believe that the continued cooperation between the Parties to reduce the potential for diversion is in the public interest, including but not limited to sharing of information related to the distribution of controlled substances; and

WHEREAS, the Parties believe that a settlement in this matter is in the public interest and desire to settle and resolve all outstanding claims and/or issues with respect to the Orders and allegations.

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein, and for other good and valuable consideration, and intending to be legally bound hereby, the Parties hereto agree as follows:

## I. General

- 1. <u>Intention of Parties to Effect Settlement</u>. In order to avoid the uncertainty and expense of litigation, the Parties agree to resolve this matter according to the Terms and Conditions below.
- 2. No Admission or Concession. This Agreement is neither an admission by McKesson of liability or of any allegations made by DEA in the Orders and investigations, nor a concession by DEA that its allegations in the Orders and investigations are not well-founded.
- 3. <u>Covered Conduct</u>. For purposes of this Agreement, "Covered Conduct" shall mean the following:
  - (i) the conduct alleged in the Orders;

- (ii) the alleged failure of McKesson to maintain adequate controls against the diversion of controlled substances, on or prior to December 31, 2007, at all distribution facilities operated, owned, or controlled by it;
- (iii) the conduct described in Appendix B, Paragraph 8 to this Agreement; and
- (iv) the alleged failure of McKesson to detect and report suspicious orders of the controlled substances as required by 21 C.F.R. § 1301.74(b) on or before December 31, 2007.
- 4. <u>DEA Headquarters</u>. For purposes of this Agreement, the DEA Representative shall be the Chief, Pharmaceutical Investigations Section, Operations Division, DEA Headquarters.
- 5. McKesson Representative. For purposes of this Agreement, the McKesson Representative shall be the Senior Vice President, Distribution Operations or the Vice President, Regulatory Affairs.

## II. Terms and Conditions

## 1. Obligations of McKesson.

- (a) McKesson agrees to maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations. This program shall include procedures to review orders for controlled substances. Orders that exceed established thresholds and criteria will be reviewed by a McKesson employee trained to detect suspicious orders for the purposes of determining whether (i) such orders should be not filled and reported to the DEA or (ii) based on a detailed review, the order is for a legitimate purpose and the controlled substances are not likely to be diverted into other than legitimate medical, scientific, or industrial channels. Orders identified as suspicious will be reported to the DEA as discussed in subsection II.1(c). This compliance program shall apply to all current and future McKesson distribution centers registered with the DEA in the United States and its territories and possessions. McKesson acknowledges and agrees that the obligations undertaken in this subparagraph do not fulfill the totality of its obligations to maintain effective controls against the diversion of controlled substances or to detect and report to DEA suspicious orders for controlled substances.
- (b) Within five (5) business days following the date of each controlled substance transaction, McKesson shall provide DEA Headquarters with a report of all controlled substance transactions through Electronic Data Interchange in a format mutually and reasonably agreed upon by the Parties. This information will be based on raw sales data and will not be reconciled in the manner that Automation of Reports and Consolidated Orders System (ARCOS) data is reconciled, nor does this requirement supplant the requirement to report ARCOS data in the time and manner required by DEA regulations. The Parties agree that the data provided in this report shall be a true and correct copy of the raw transaction data at the time that the data is transmitted to the DEA and thus does not contain any adjustments or corrections that would normally be part of McKesson's reconciliation of its business records. The Parties agree that the report does not

otherwise constitute the basis for McKesson's compliance with recordkeeping and reporting requirements under the CSA or applicable DEA regulations. The Parties agree that such report is not required under the CSA or DEA regulations and that the accuracy of the report or the failure to file such a report is not a basis for a violation of 21 U.S.C. § 842(a)(5). McKesson shall begin transmitting this information no later than 120 days after the Parties have mutually agreed upon a format. The obligations contained in this paragraph shall remain in full force and effect for a period of five (5) years from the Effective Date of this Agreement unless DEA agrees in writing to an earlier termination of the obligations contained in this paragraph.

- (c) McKesson shall inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b) in a format mutually and reasonably agreed upon by the Parties, except that contrary to DEA regulations, McKesson shall inform DEA Headquarters rather than the local DEA Field Office of suspicious orders, unless and until advised otherwise in writing by DEA Headquarters. DEA agrees to notify all of the DEA Field Offices within 30 days of the Effective Date of this Agreement that McKesson will no longer be required to provide suspicious order reports or any other type of reports regarding excessive purchases of controlled substances to the DEA Field Offices and that this Agreement shall supersede any DEA regulatory requirements to report suspicious orders to DEA. The obligations contained in this paragraph shall be and remain in full force and effect from the Effective Date of this Agreement, and thereafter shall remain in full force and effect unless terminated and revoked by DEA with thirty (30) days written notice.
- (d) McKesson agrees to a temporary suspension of its authority to distribute drugs containing the drug codes for Schedule III hydrocodone combination products and alprazolam, that is, DEA drug codes 9805, 9806 and 2882 with respect to the DEA registrations for its Lakeland Facility and its Conroe Facility, except for sales to the accounts as listed in Appendix C. The temporary suspension shall terminate in accordance with subsection II.2(g) unless sooner terminated by the Parties in writing pursuant to the terms of this Agreement.
- (e) McKesson agrees that any express or implied approval by DEA of any previously implemented system to detect and report suspicious orders, is hereby rescinded and is of no legal effect with respect to McKesson's obligations to detect and report suspicious orders in accordance with 21 C.F.R. §1301.74(b).
- (f) McKesson agrees that within 120 days of the Effective Date of this Agreement it will review distributions of hydrocodone and alprazolam for the 24-month period immediately preceding the execution of this Agreement and identify any current customer whose purchases of hydrocodone and alprazolam exceeded the thresholds established in its compliance program. McKesson shall conduct an investigation and take appropriate action as required by this Agreement, DEA regulations and other procedures established under McKesson's compliance program including its Controlled Substance Monitoring Program (CSMP).
- (g) McKesson's policy and procedure is to cooperate with the government in any investigation. McKesson agrees to reasonably cooperate with DEA, the United States Attorneys' Offices, and any other Federal, state, or local law enforcement agency investigating or prosecuting McKesson's customers for alleged violations or activities related to the Covered Conduct unless such matters would affect the rights or obligations of McKesson in regard to any

pending or threatened litigation. Such cooperation shall include, but is not limited to, producing records and making employees available for interviews by the DEA or other law enforcement authorities. However, nothing in this paragraph shall be construed as a waiver by McKesson or its employees of any constitutional rights or rights that the company would have as a party to a matter involving pending or threatened litigation with the government or a third party.

- (h) McKesson agrees to pay civil penalties to the United States of America under 21 U.S.C. § 842(c) for violations of 21 U.S.C. § 842(a)(5) in the amount of \$13,250,000.00 in settlement of claims or potential claims made by the United States of America for failing to report suspicious orders of controlled substances and for failing to report thefts or significant losses of controlled substances. Payment of said civil penalties shall be made by McKesson in the amounts indicated and as directed by the United States Attorneys' Offices set forth in Appendix B, Paragraph 13. McKesson agrees to execute the Settlement Agreement at Appendix B simultaneously with the execution of this Agreement and to execute any other documents necessary to fully and finally settle all claims of the United States of America under this subparagraph, and to fully pay said civil penalties within 30 days of the Effective Date of this Agreement.
- (i) Any material breach by any McKesson facility of subsections II.1(a)-(h) of this Agreement by McKesson after the Effective Date of this Agreement may be a basis upon which DEA can issue an Order to Show Cause seeking the revocation of McKesson's DEA certificate(s) of registration for that facility.

### 2. Obligations of DEA.

- (a) At McKesson's request, DEA shall continue to provide diversion prevention and awareness training, as practicable, to retail pharmacy industry members at McKesson trade shows and through written materials. The frequency and content of such training shall be at DEA's sole discretion.
- (b) DEA agrees to accept at DEA Headquarters the information regarding suspicious orders as required under 21 C.F.R. §1301.74(b) and described in subsection II.1(c) of this Agreement. DEA agrees that this procedure is consistent with DEA regulatory requirements and hereby waives the regulatory requirement to report suspicious orders of controlled substances to the DEA Field Division Offices.
- (c) DEA agrees and acknowledges that neither the CSA, DEA regulations, nor the terms of this Agreement establish a requirement that reporting of a suspicious order means that a customer be designated as a suspicious customer that would de facto require the suspension of all orders or sales of other controlled substances to this customer.
- (d) DEA agrees that any request made by DEA or any of its employees that McKesson continue to sell controlled substances to customers for an order that McKesson has determined to be suspicious shall be made in writing to the designated McKesson Representative.

- (e) Within 150 days of the Effective Date of this Agreement, but not earlier than 90 days after the Effective Date of this Agreement, DEA shall conduct reviews of the functionality of McKesson's diversion compliance program ("Compliance Reviews") at up to eight distribution centers of McKesson, consisting of the Lakeland Facility; the Landover Facility; the Conroe Facility; and five other McKesson distribution centers selected by DEA. DEA shall also review the investigatory files maintained by McKesson of the customers serviced by the distribution centers subject to the Compliance Reviews. DEA shall notify McKesson no less than 48 hours prior to commencing a Compliance Review at a distribution center. DEA shall issue a Notice of Inspection to McKesson upon commencement of a Compliance Review. During the course of a Compliance Review, if requested, McKesson shall provide DEA with information related to the sales of controlled substances, non-controlled drugs, and listed chemicals from Effective Date of Agreement, to the date of the Compliance Review by the particular distribution center being reviewed. At the conclusion of each Compliance Review, DEA shall conduct an exit interview with an appropriate McKesson representative to provide DEA's preliminary conclusions regarding the Compliance Review.
- (f) The Compliance Reviews will be deemed satisfactory unless DEA determines that one or more of the facilities being inspected has (i) failed to maintain effective controls against diversion regarding the distribution of any controlled substance; (ii) failed to detect and report to DEA suspicious orders of controlled substances; or (iii) failed to meaningfully investigate new or existing customers regarding the customer's legitimate need to order or purchase controlled substances. The Compliance Reviews shall be deemed "not satisfactory" if DEA provides written notice with specificity to McKesson on or before 165 days from the Effective Date of Agreement, stating that McKesson failed to meet any of the requirements in either subsections II.2(f)(i), (ii), or (iii) of this Agreement. DEA shall not find a Compliance Review "not satisfactory" unless the failure(s) are sufficient to provide DEA with a factual and legal basis for issuing an Order to Show Cause under 21 U.S.C. § 824(a) against one or more of the inspected facilities. In the event that DEA provides such written notice of a Compliance Review Failure(s), DEA shall meet and confer with McKesson within 48 hours regarding such a finding. DEA shall consider remedial measures that McKesson has instituted in determining whether the Compliance Reviews are satisfactory. A finding of "satisfactory" does not otherwise express DEA's approval of the compliance program implemented at any particular distribution center.
- (g) Upon the completion of the Compliance Reviews and within 180 days of the Effective Date of this Agreement, DEA will restore the drug codes 9805, 9806 and 2882 to the DEA registrations for the Lakeland and Conroe Facilities. In the event that McKesson has not satisfied DEA in regard to the Compliance Reviews within 180 days of the Effective Date of this Agreement and DEA issues a Show Cause against either of the Lakeland or Conroe Facilities, McKesson agrees to a new period of suspension of the drugs codes at such facility until the matter is resolved by mutual agreement of the Parties or a final decision by the DEA Deputy Administrator. Notwithstanding, nothing in this Agreement shall prevent the Parties from agreeing to an extension or shortening of the suspension period for these drugs codes at the Lakeland and Conroe Facilities at any time during the course of this Agreement. DEA shall not be prevented from taking any action that would otherwise be available to the agency to pursue a new period of suspension of the drug codes at these facilities.

- (h) DEA shall execute this Agreement only upon obtaining a fully executed copy of the Settlement Agreement at Appendix B.
- (i) In the event that DEA discovers information that may warrant administrative action, and which is not otherwise included under the Covered Conduct, DEA shall favorably consider McKesson's entry into this Agreement; all actions taken by McKesson pursuant to this Agreement; any remedial actions taken by McKesson to address the alleged or perceived violative conduct; and the compliance history of McKesson at the particular facility and at other McKesson facilities.
- (j) DEA represents that it has reviewed its records for investigations or inspections, initiated or conducted prior to December 31, 2007, which may allege that McKesson failed to report suspicious orders as required by 21 C.F.R. 1301.74(b). DEA further represents that it has reviewed reports and records submitted by McKesson to DEA on or before December 31, 2007 for indications that McKesson may have failed to report suspicious orders as required by 21 C.F.R. 1301.74(b). DEA has not referred and agrees to not refer any conduct (other than conduct in Appendix B, Paragraph 8) occurring before December 31, 2007, for civil penalty proceedings under to 21 U.S.C. § 842(a)(5) that would be based on the Covered Conduct, to any other agency within the Department of Justice.
- 3. <u>Joint Obligations of the Parties</u>. McKesson and DEA agree that upon the execution of this Agreement, DEA and McKesson shall file a joint motion with the DEA Administrative Law Judge to terminate all pending administrative proceedings against the Lakeland Facility and Landover Facility.
- 4. Release by DEA. (i) In consideration of the fulfillment of the obligations of McKesson under this Agreement, DEA agrees to:
  - (i) Release McKesson from any administrative claims within DEA's enforcement authority for the conduct alleged in the Orders; and
  - (ii) Refrain from filing any administrative claims against McKesson within DEA's enforcement authority under21 U.S.C. §§ 823, 824 and 842, based on the Covered Conduct, only to extent that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of open investigations and inspections in existence as of December 31, 2007, and the review of the reports and records McKesson submitted to DEA prior to December 31, 2007.

Notwithstanding the releases by DEA contained in this Paragraph, DEA reserves the right to seek to admit evidence of the Covered Conduct in any other administrative proceedings. Further, nothing in this Paragraph shall prohibit any other agency within the Department of Justice, any State attorney general, or any other law enforcement, administrative, or regulatory agency of the United States or any State thereof ("law enforcement agency"), from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct and DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any law enforcement

agency that initiates an investigation, action, or proceeding involving the Covered Conduct. At McKesson's request, DEA agrees to disclose the terms of this Agreement to any other law enforcement agency and will represent that McKesson's compliance with this Agreement adequately addressed the administrative and civil allegations raised by DEA as defined in the Covered Conduct. This release is applicable only to the Released Parties and is not applicable in any manner to any other individual, partnership, corporation, or entity.

- 5. Release by McKesson. McKesson fully and finally releases the United States of America, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which McKesson has asserted, could have asserted, or may assert in the future against the United States of America, its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.
- 6. Reservation of Claims. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including McKesson) are the following:
- (a) Any civil, criminal or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);
- (b) Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct subject to Paragraph II.4 of this Agreement; or
  - (c) Any liability based upon such obligations as are created by this Agreement.

## III. Miscellaneous

- 1. <u>Binding on Successors</u>. This Agreement is binding on McKesson, and its respective successors, heirs, transferees, and assigns.
- 2. <u>Costs</u>. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.
- 3. No Additional Releases. This Agreement is intended to be for the benefit of the Parties and the Released Parties only, and by this instrument the Parties do not release any claims against any other person or entity other than the Released Parties.
- 4. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement, and each of the parties expressly agrees and acknowledges that, other than those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transactions contemplated by this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties.

McKesson represents that this Agreement is entered into with advice of counsel and knowledge of the events described herein. McKesson further represents that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion.

- 5. Execution of Agreement. This Agreement shall become effective (i.e., final and binding) five (5) business days after the date of signing by the last signatory (the "Effective Date"). The government agrees to notify McKesson immediately when the final signatory has executed this Agreement.
- 6. <u>Disclosure</u>. McKesson and DEA may each disclose the existence of this Agreement and information about this Agreement to the public without restriction. However, the Parties agree to provide each other with advance notice the day before or as soon as possible once a decision has been made to issue any public statement or press release related to this Agreement. The Parties shall provide copies of any press release no later than two hours before issuing the press release. This paragraph does not apply to any press release or public statement issued by the Department of Justice or any United States Attorney's Office. This paragraph shall remain in effect for sixty (60) days, commencing with the Effective Date of the Agreement.
- 7. Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement.
- 8. <u>Authorizations</u>. The individuals signing this Agreement on behalf of McKesson represent and warrant that they are authorized by McKesson to execute this Agreement. The individuals signing this Agreement on behalf of DEA represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA to execute this Agreement.
- 9. Choice of Law and Venue. This Settlement Agreement and Release shall be construed in accordance with the laws of the United States, and either Party may seek judicial enforcement of this Agreement upon a material breach by the other Party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties under subsections II(2)(a-d) of this Agreement will be the United States District Court or, as appropriate, in the Court of Federal Claims, in which the McKesson distribution facility(s) at issue is located. This provision, however, shall not be construed as a waiver of the jurisdictional provisions of the Controlled Substances Act.

IN WITNESS WHEREOF, the Parties hereto have duly executed this Settlement and Release Agreement as of the date written above.

MCKESSON CORPORATION

Oph Hammergren

President

McKesson Corporation

Dated: April 28, 2008

By: Oolbellus

Donald G. Walker Senior Vice President McKesson Corporation

Dated: April 30, 2008

THE UNITED STATES DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT/ADMINISTRATION

By: \_\_\_\_

Michele M. Ldon/an Acting Administrator

Drug Enforcement Administration

By:

Wendy HJ Goggin

Chief Counsel

Drug Enforcement Administration

Dated: May 2, 2008

Dated: May /\_\_, 2008

## Appendix A

## McKesson Distribution Center DEA Registered Facilities

Location	DEA Registration #
Carol Stream, IL	RM0220599
Methuen, MA	PM0020850
West Seneca, NY	PM0003094
Everett, WA	PM0150538
Anchorage, AK	RM0227430
Aurora, CO	PM0018425
Livonia, MI	PM0030849
Honolulu, HI	PM0001014
Santa Fe Springs, CA	PF0000012
Duluth, GA	PR0040357
Memphis, TN	PM0001951
Washington Ct. House, OH	RM0220688
Oklahoma City, OK	RM0138328
La Vista, NE	PM0038693
Tolleson, AZ	PM0021131
Wilsonville, OR	PM0022929
La Crosse, WI	RM0220537
Delran, NJ	RM0173055
Salt Lake City, UT	PM0023046
West Sacramento, CA	PM0021535
O'Fallon, MO	PM0037374
Memphis, TN	RM0207286
Lakeland, FL	PM0000771
New Castle, PA	RM0258601
Landover, MD	PD0029567
Aberdeen, SD	RM0335869
Conroe, TX	RM0328408
McCalla, AL	RM0336950
Little Canada, MN	PM0036334
Cape Girardeau, MO	RM0337534
Rocky Hill, CT	PR0104593
Aurora, CO	RM0354958

## Appendix B

## SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into this \_\_\_\_\_\_ day of April, 2008, by and between the United States Department of Justice, through the United States Attorney's Offices for the Districts of Maryland, Middle Florida, Southern Texas, Colorado, Utah and Eastern California ("United States") and McKesson Corporation including facilities doing business as McKesson Pharmaceuticals and McKesson Drug Company, ("McKesson") and collectively referred to as "the Parties."

#### RECITALS

- 1. McKesson is a Delaware corporation and is headquartered in San Francisco, California. Among other things, McKesson is in the business of distributing branded and generic prescription drugs, as well as over-the-counter medications, to retail pharmacies throughout the United States. In furtherance of this business objective, McKesson operates numerous distribution facilities in the United States, including six facilities more fully described in Attachment A to this Agreement ("the Six Facilities").
- 2. As more fully described in Attachment A, McKesson holds Certificates of Registration issued by the Drug Enforcement Administration ("DEA") authorizing it to distribute controlled substances from these facilities including the Six Facilities.
- 3. McKesson is required to operate the Six Facilities in accordance with the statutory and regulatory provisions of the Controlled Substances Act, 21 U.S.C. § 801 et seq. ("the CSA").
- 4. Each of the Six Facilities supplies prescription medications, including controlled substances, to retail pharmacies and other health care providers within the respective

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jurisdictions as stated in Paragraph 8.

- 5. DEA is the Department of Justice component agency primarily responsible for administering the CSA and is vested with the responsibility of investigating CSA violations.
- 6. The Attorney General, through the United States Attorneys, has primary authority to bring civil actions to enforce the CSA in the Districts noted above. See 21 U.S.C. § 871 and 28 C.F.R. § 0.55(c).
- 7. Methadone, Hydrocodone, Phentermine, Fentanyl and Oxycodone are medications whose manufacture, distribution, sale and possession are regulated by DEA under the CSA. This includes a requirement to report customer orders for controlled substances that are suspicious as the term is defined under 21 C.F.R. §1301.74(b).
- 8. The "Covered Conduct" shall mean the following alleged conduct:
  - A. Within the District of Maryland: From January 2005 through October 2006, McKesson-Landover sold approximately 3 million dosage units of hydrocodone to NewCare Pharmacy in Baltimore, and failed to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). Further, from August 2006 to February 2007, McKesson-Landover sold large quantities of phentermine based products to Smeeta Pharmacy in Highland, Maryland and failed to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5);
  - B. Within the Middle District of Florida; In October 2005, McKesson-Lakeland sold approximately 2.1 million dosage units of hydrocodone to seven pharmacies in the Tampa area (Trelles Pharmacy, BiWise Drugs, Universal RX, United Prescription Service, Accumed Rx Medipharm RX and Avee Pharmacy) and failed to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5);
  - C. Within the Southern District of Texas: From February to September 2007, McKesson-Conroe sold approximately 2.6 million dosage units of hydrocodone to Mercury Drive Pharmacy and Maswoswe's Alternative Pharmacy and failed to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5);

- D. Within the District of Colorado: From September 2005 through November 2007, McKesson-Aurora sold large quantities of hydrocodone to three Colorado pharmacies (Brighton Pharmacy in Brighton, Colorado; Western States Pharmacy in Brighton, Colorado; and St. Vrain's Pharmacy in Lyons, Colorado), and failed to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5);
- E. Within the District of Utah: From January 2005 through October 2007, McKesson-Salt Lake City sold approximately 824,000 dosage units of hydrocodone, Oxycodone, Fentanyl and Methadone to the Blackfeet Clinic in Browning, Montana, and failed to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5);
- F. Within the Eastern District of California: From October 2007 through June 2007, McKesson-West Sacramento suffered the theft or significant loss of controlled substances on twenty-eight separate occasions, and failed to timely submit required theft and loss reports to DEA, in violation of 21 C.F.R. §§ 1301.74(c) and 1301.76(b), and 21 U.S.C. § 842(a)(5).
- 9. By entering into this Agreement, McKesson does not admit to the violations alleged as a result of any DEA investigation, or to any violation of law, liability, fault, misconduct, or wrongdoing. McKesson explicitly denies any allegations of violations of the CSA or DEA regulations and represents that the company has defenses to the violations alleged by the government.
- 10. At all times relevant to the activity alleged in these Recitals and Attachments, the CSA (21 U.S.C. § 842(c)(1)), authorized the imposition of a civil penalty of up to \$25,000 for each violation of the Section, except that violations of § 842(a)(5) (record keeping and reporting violations) are subject to a civil penalty of up to \$10,000 for each violation.
- 11. To avoid the delay, expense, inconvenience and uncertainty of litigation of these claims, the Parties agree to settle, compromise, and resolve all existing or potential claims for civil penalties the United States may have against McKesson under § 842 of the CSA based on the Covered Conduct as further described in Paragraphs 13 and 14 below.

12. This Agreement is neither an admission of liability by McKesson nor a concession by the United States that its claims are not well founded. In consideration of the mutual promises, covenants, and obligations set forth in this Agreement, the Parties agree as follows:

## **TERMS AND CONDITIONS**

- 13. McKesson shall pay to the United States the sum of Thirteen Million, Two Hundred Fifty Thousand Dollars (\$13,250,000) (the "Settlement Amount") within thirty (30) days of the effective date of this Agreement, payable as follows:
  - A. <u>For Conduct Alleged to have Occurred within the District of Maryland:</u> McKesson shall pay the sum of Two Million Dollars (\$2,000,000). Payment shall be by electronic funds transfer to the United States Attorney's Office, District of Maryland, pursuant to instructions provided by the United States.
  - B. For Conduct Alleged to have Occurred within the Middle District of Florida: McKesson shall pay the sum of Seven Million Four Hundred Fifty-Six Thousand Dollars (\$7,456,000). Payment shall be by electronic funds transfer to the United States Attorney's Office, Middle District of Florida, pursuant to instructions provided by the United States.
  - C. For Conduct Alleged to have Occurred within the Southern District of Texas: McKesson shall pay the sum of Two Million Dollars (\$2,000,000). Payment shall be by electronic funds transfer to the United States Attorney's Office, Southern District of Texas, pursuant to instructions provided by the United States.
  - D. <u>For Conduct Alleged to have Occurred within the District of Colorado:</u> McKesson shall pay the sum of One Million Dollars (\$1,000,000). Payment shall be by electronic funds transfer to the United States Attorney's Office, District of Colorado, pursuant to instructions provided by the United States.
  - E. <u>For Conduct Alleged to have Occurred within the District of Utah:</u> McKesson shall pay the sum of Five Hundred Forty-Four Thousand Dollars (\$544,000). Payment shall be by electronic funds transfer to the United States Attorney's Office, District of Utah, pursuant to instructions provided by the United States.
  - F. For Conduct Alleged to have Occurred within the Eastern District of California: McKesson shall pay the sum of Two Hundred Fifty Thousand Dollars (\$250,000). Payment shall be by electronic funds transfer to the United States Attorney's Office,

Eastern District of Callfornia, pursuant to instructions provided by the United States.

14. In consideration of the undertakings by McKesson, the United States agrees to settle and relinquish all claims for civil penalties it may have under 21 U.S.C. § 842(c)(1) against McKesson, its officers, directors, and employees for possible violations of the CSA,

and the regulations promulgated thereunder, based on the Covered Conduct.

15. McKesson fully and finally releases the United States, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which it has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and

agents, related to the investigation, prosecution and settlement of this matter.

16. Notwithstanding any term of this Agreement, specifically reserved and excluded from its scope and terms as to any entity or person are the following:

A. Any potential criminal liability;

B. Any criminal, civil or administrative claims arising under Title 26, U.S. Code (Internal Revenue Service);

C. Any administrative liability, including mandatory exclusion from any federal programs;

D. Any liability to the United States for any conduct other than that covered by the release in Paragraph 14; and

E. Any claims based on such obligations as are created by this agreement.

17. McKesson acknowledges that each of its DEA registered facilities is required to comply with the controlled substance record keeping and reporting requirements of the CSA. McKesson represents that it has taken good-faith actions to detect and prevent

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diversion including agreeing to implement the policies and procedures that are the subject

of an administrative settlement agreement between it and DEA dated May 🚣 , 2008.

18. McKesson agrees that any and all costs it has or will incur in connection with this

matter-including payment of the Settlement Amount under this Agreement, attorney's fees,

costs of investigation, negotiation, and remedial action-shall be unallowable costs for

government contract accounting and for Medicare, Medicaid, TriCare, and FEHBP

reimbursement purposes.

19. This Agreement is not intended by the Parties to be, and shall not be interpreted to

constitute, a release of any person or entity not identified or referred to herein.

This Agreement shall be governed by the laws of the United States. If a dispute

arises under this Agreement between McKesson and an Office of the United States

Attorney signing this Agreement, exclusive jurisdiction and venue shall lie in the federal

judicial district of the Office with whom the dispute arose, and to the extent that state law

applies to the dispute, the law of the State within the jurisdictional district shall apply. If a

dispute arises under this Agreement between McKesson and more than one of the United

States Attorney's Office signing this Agreement, exclusive jurisdiction and venue shall lie

in the District of Maryland and to the extent that state law applies to the dispute, the law of

Maryland shall apply.

21. The Parties agree that this Agreement does not constitute evidence or an admission

by any person or entity, and shall not be construed as an admission by any person or

entity, with respect to any issue of law or fact.

22. This Agreement constitutes the entire agreement between the Parties and cannot

be amended except in writing and when signed by all the Parties to this Agreement.

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- 23. McKesson acknowledges that its authorized representatives have read this Agreement and understand that as of its effective date, it will be a matter of public record.
- 24. Each person who signs this Agreement in a representative capacity warrants that he or she is fully authorized to do so.
- 25. This Agreement shall be effective on the date of signing by all the Parties. It may be executed in counterparts, each of which shall constitute an original and all of which shall constitute one and the same agreement.

On Behalf of McKesson Corporation One Post Street

San Francisco, California 94104

John H. Hammergren

President

Dated: Apr. / 28 . 2008

Donald G. Walker Senior Vice President

Dated: April 30 . 2008

John A. Gilbert, Jr.

Hyman, Phelps & McNamara, P.C.

Counsel to McKesson Corporation

Dated: Knu-125 , 2008

On Behalf of the United States

ROD J. ROSENSTEIN United States Attorney District of Meryland

Micheel A. DiPlato Assistant United States Altomey

Dated: April 21/2008

Dated: April 29

ROBERT E. ONEILL United States Atlamey Middle District of Florida

Javiè Guzman

Assistant United States Attorney

Dated: April 21\_ 2008

DONALD J. DeGABRIELLE United States Afformay Southern District of Texas

Assistant United States Altomey

2008 (Select: April 2008)

TROY A. EID United States Attorney District of Colorado

Amenda Rocque Assistant United States Attorney

Oaled: April-27. 2008

BRETT L. TOLMAN United States Attorney

Olstrict of Utahi

Eric A. Overby

Assistant United States Attorney

McGREGOR W. SCOTT United States Attorney Eastern District of California

Catherine Swann

Assistant United States Altomey

Dated: April 27, 2008

#### ATTACHMENT A

## (Six McKesson Facilities Referenced in Paragraph 1 of this Agreement)

- 1. 7721 Polk Street in Landover Maryland ("McKesson-Landover"), located within the District of Maryland and operating under DEA registration number PD0029567;
- 1515 West Bella Vista Street in Lakeland Florida ("McKesson-Lakeland"), located within the Middle District of Florida and operating under DEA registration number PM 0000771;
- 3. 3301 Pollock Drive in Conroe Texas ("McKesson-Conroe"), located within the Southern District of Texas and operating under DEA registration number RM 0328408;
- 4. 14500 East 39<sup>th</sup> Avenue in Aurora Colorado ("McKesson-Aurora"), located within the District of Colorado and operating under DEA registration number PM 0018425;
- 5. 1900 South 4490 West in Salt Lake City Utah ("McKesson-Salt Lake City"), located within District of Utah and operating under DEA registration number PM0023046; and
- 6. 3775 Seaport Boulevard in West Sacramento California ("McKesson-West Sacramento"), located within the Eastern District of California and operating under DEA registration number PM 0021535.

Appendix C - Sales Accounts at Lakeland and Conroc Facilities authroized by DEA as an exception to Paragraph II.1(d). (Lakeland DC Code = 195/Conroc Code = 115)

Account Name	DC DEA	Address	City	St	Ζιρ
CENTRAL TX VA-SPD TEMPLE	115 AB4451124	1901 SOUTH FIRST STREET	TEMPLE	TX	76504
VA MED CTR CII PINEVILLE	115 AD3351070	2495 SHREVEPORT HWY	PINEVILLE	LA	71360
FCI SEAGOVILLE	115 AF2404527	2113 NORTH HIGHWAY 175	SEAGOVILLE	TX	75159
FCI MIAMI	195 AF6804733	15801 SW 137TH AVENUE	MIAMI	FL.	33177
FCI BASTROP	115 AF8942650	1341 HIGHWAY 95 NORTH	BASTROP	TX	78602
USPHS HOSPITAL UNIT-PCI	195 AK4351982	FED COR/501 CAPITAL CRINE	TALLAHASSEE	FL	32301
US PUBLIC HEALTH SERVICE	195 AU1434911	18201 SW 12 STREET	MIAMI	FL.	33194
VA OP CLINIC PHARMACY	195 AV1230313	5599 N DIXIE HIGHWAY	OAKLAND PARK	PL	33334
VA LAKE CITY OUTPATIENT	195 AV4277845	619 S MARION STREET	LAKE CITY	FL	32025
VA MEDICAL CENTER/INPAT	195 AV4345559	1201 NW 16111 ST	MIÁMI	FL	33125
VA MEDICAL CENTER OF PHCY	115 AV4515790	2002 HOLCOMBE BLVD	HOUSTON	TX	77030
VA MEDICAL CENTER-CII	115 AV4515815	510 EAST STONER AVE	SHREVEPORT	I.A	71101
VA MED CIR GAINESVILLE IP	195 AV4671372	1601 SW ARCHER ROAD	GAINESVILLE	FL	32608
CENTRAL TX VETS-CONT WACO	115 AV4718714	4800 MEMORIAL DRIVE	WACO	TX	76711
VA OUTPATIENT CLINIC	195 AV5214488	1833 BOULEVARD	JACKSONVILLE	Fi.	32206
VA MEDIÇAL CENTER I/P	195 AV5307889	10000 BAY PINES BLVD	SAINT PETERSBURG	FI.	33708
VA MEDICAL CTR-KERRVILLE	115 AV5318856	3600 MEMORIAL DRIVE	KERRVILLE	TX	78028
VA MEDICT IP-AUDIE MURPHY	115 AV5546936	7400 MERTON MINTER BLVD	SAN ANTONIO	TX	78229
VA MC I/I'-O/I' NEW ORLEANS	115 AV6767719	1601 PERDIDO ST/RM#1F157	NEW ORLEANS	LA	70112
VA O/P CLINIC BEAUMONT	115 AV7507164	3420 VETERAN CIRCLE	BEAUMONT	1.7.	77707
VA OUTPATIENT CLIN A&MMS	195 AV8635469	3033 WINKLER AVE EIT	FORT MYERS	FL.	33916
VA OUTPATIENT CLINIC	115 AV9426760	7968 ESSEN PARK AVE	BATON ROUGE	LA	70809
ALA-COUSHATTA INDIAN IIIS	H5 DA7647502	129 DAYCARE ROAD	LIVINGSTON	TX	77351
FEDERAL PRISON CAMP PENSC	195 BB1595911	FED PRISON CAMP PENSCOLA	PENSACOLA	M	32509
MICCOSUKEE HETH CIR HIS	195 BB3849518	MILE MARKER 70, US HWY 41	MIAMI	M	33144
COUSHATTA HLT DEPART THS	115 BC6820383	PO BOX 519 2003 CC BEL RO	ELTON	LA	70532
DEPT OF VET AFFAIRS MED	195 BD2256990	10 CALLE CASIA	SANJUAN	PR	921
VA MEDICAL CENTER	195 HD2669995	7305 NORTH MILITARY TRAIL	WEST PALM BEACH	FL	33410
VA OUTPATIENT CLINIC	195 BD4632015	5201 RAYMOND STREET	ORLÁNDO	FL.	32803
VETS NURSING HM/FL SVH2	195 BQ5967180	1920 MASON AVENUE	DAYTONA BEACH	FL	32117
BALDOMERO LOPEZ MEM SVH2	195 BD6136534	6919 PARKWAY BLVD	LAND O LAKES	PL	34639
FED PRISON CMP BRYAN	11S DF1742332	1100 URSULINE	BRYAN	TX	77803
FED DETENTION ONT OAKDALE	115 BF2225589	POB BOX 5060 E WHATLEY RD	OAKDALII	LA	71463
PCI THREE RIVERS	115 012295017	PO BOX 4000 HWY 72 WEST	THREE RIVERS	TX	78071
FED DETENTION ONT MIAMI	195 BF3780219	33 NE 4TH STREET	MIAMI	FL.	33132
FED CORR CMP COLEMAN	195 BF4461783	811 NE 54TH TERRACE	COLEMAN	FL	33521
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## Appendix C - Sales Accounts at Lakeland and Conroe Facilities authroized by DEA as an exception to Paragraph II.1(d). (Lakeland DC Code = 195/Conroe Code = 115)

FED DETENTION CTR HOUSTON	115 BF64\$1\$06	1200 TEXAS AVENUE	HOUSTON	TX	77002
US PENITENTIARY-POLLOCK	115 131-7167845	POB 1000 1000 AIR BASE RD	POLLOCK	LA	71467
ALEXANDER NININGER SVII2	195 13177171589	8401 W CYPRESS DR	PEMBROKE PINES	FL.	33025
CLIFFORD CHESTER SIMSSVIIZ	195 BF8568909	4419 TRAM ROAD	SPRINGFIELD	FL.	32404
D.T. JABSON ST NH SVH2	195 BF8646816	21281 GRAYTON TERRACE	PORT CHARLOTTE	FL	33954
HARLINGEN VA OUTPT CLINIC	115 BH9206714	2106 TREASURE HILLS BLVD	HARLINGEN	TX	78550
INS DETENTION FACILITY	115 B12613885	BUENA VISTA ROAD	BAYVIEW	TX	78566
IMMIGRATIONS & CUSTOMS VA	115 BI8861367	15850 EXPORT PLAZA DRIVE	HOUSTON	TX	77032
IMMIGRAT&CUSTOMS/PEARSALL	115 BI9144457	566 VETERANS DRIVE	PEARSALL	TX	78061
JAMES A HALEY/VA MED I/P	195 BJ0413839	13000 BRUCE B DOWNS BLVD	TAMPA	r.	33612
FCIMARIANNA	195 BM1291347	3625 FCJ ROAD	MARIANNA	FL.	32446
NORTH CENTRAL FED CLINIC	115 BN9966500	17440 HENDERSON PASS	SAN ANTONIO	TX	78232
POARCH BAND-CREEK IND IHS	195 BP1332080	5811 JACK SPRINGS RD	ATMORE	AL	36502
CHITIMACHA HLTH&HUMAN IIIS	115 BP7040176	3231 CHITIMACHA TRAIL	CHARENTON	LA	70523
SNH BYAMC/BAY MINETT SVH2	195 B\$7636698	300 FAULKNER DRIVE	BAY MINETTE	AL.	36507
SW LA WAR VETERANS HOME	115 BS9016379	1610 EVANGELINE HWY	JENNINGS	LA	70546
USPIIS IMMIGRATION CUSTOMS	115 BU9827140	1001 WELCH STREET	TAYLOR	TX	76574
USPHS MEDICAL CLINIC BICE	115 BU9834640	1800 INDUSTRIAL DRIVE	RAYMONDVILLI	TX	78580
V A OUTPATIENT CLINIC	195 BV0255706	551 NATIONAL HLTH CARE DR	DAYTONA BEACH	r.	32114
VA MAYAGUEZ OUTPAT CLINIC	195 BV0366787	STATE RD 2, KM, 156,2	MAYAGUEZ	PR	680
VA MC PHCY O/P/PENSACOLA	195 BV0464761	312 KENMÖRE RD / RM 1G222	PINSACOLA	FL	32503
VA OP CLIN-CORPUS CHRISTI	115 BV 1253739	5283 OLD BROWNSVILLE ROAD	CORPUS CHRISTI	TX	78405
VA OP CIJNIC-FRANK TEJEDA	115 BV1276206	5788 ECKHERT ROAD	SAN ANTONIO	TX	78240
VA PONCE OUTPAT CLINIC	195 BV 1501700	1010 PASEO DEL VETERANO	PONCE	PR	716
VA OUTPATIENT CLINIC	115 BV2325644	1301 WEST FRANK STREET	LUFKIN	TX	75904
VA OIP CLINIC - AUSTIN	115 BV2524913	2901 MONTOPOLIS DRIVE	AUSTIN	TX	78741
VA M/C PHCY O/P MOBILE	195 BV2658687	1504 SPRINGHILL AVE #1504	MODILE	ΛL	36604
VA OUTPAT CLINIC-MCALLEN	115 BV2813182	2101 S COLONEL ROWE BLVD	MCALLEN	TX	78503
VA OUTPATIENT CLINIC	195 BV3465970	1607 ST JAMES COURT	TALLAHASSEE	n.	32308
VA OUTPATIENT CLINIC	195 BV4345319	9912 LITTLE ROAD	NEW PORT RICHEY	FL.	34654
VA OUTPATIENT CLINIC	195 BV6325852	2900 VETERANS WAY	VIERA	FL.	32940
VA COMM BASED OUTPAT CLIN	195 BV7743241	ROUTE #2 BAY 15-17	KINGSHILL	VI	850
NW LA WAR VETERANS HOME	115 FN0209103	3130 ARTHUR RAY TEAGUE PK	BOSSIER CITY	LA	71112
SE LA WAR VETS HOME	115 FS0318685	4080 WEST AIRLINE HIGHWAY	RESERVE	LA	70084
USPHS IMMIGRATION JENA	115 FU0594350	830 PINEHILL ROAD	JENA	LA	71342
SUBSTANCE DEPEND TREAT PR	115 PV0122161	2002 HOLCOMBE BLVD	HOUSTON	TX	77030
VA MEDICAL CTR DETOX	115 RS0222480	7400 MERTON MINTER BLVD	SAN ANTONIO	TX	78229

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**VA FOXTROT** 

195 RV0329688 401 GILLIS DRIVE

ORLANDO

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